

thickness X cm, a width Y cm, and a length Z cm, wherein $X * Y * Z$ is less than 12 cm³, preferably less than 2 cm³ and more preferably less than 1 cm³).

Figure 2 illustrates the assay test components of the assay test shown in Figure 1. The assay test comprises three main parts, a base 16, a middle 20, and a top 21.

5 The base 16, middle 20, and top 21 are constructed of a strong, durable material such as plastic, although a variety of materials are contemplated by the present invention. In this figure, the attachments to the base 16 include a hinge 15, two filter avenues 18, a well covering 40, an absorbent material 42, and a reaction means impregnated on a thin sheet 14 for detecting the presence of alcohol in a sample. The hinge 15 is constructed in conjunction with the base 16 to form a single molded part. The hinge is made of a thin, flexible material such as plastic, although a variety of materials are contemplated by the present invention. The hinge 15 allows the well covering 40 to easily fold, snap, and lock onto the well 38 on the middle section 20. The hinge 15 also allows the absorbent material 42 to easily fold into the well 38. The filter avenues 18 allow the fluid sample from the absorbent material to travel up both sides of the base 16. A material or body that draws a fluid sample such as filter paper or small capillary tubes is used to construct the filter avenues 18. The well covering 40 is constructed in conjunction with the base 16 to form one molded part. The absorbent material 42 is constructed of a material that absorbs and collects a desired fluid sample (e.g., saliva) such as a synthetic sponge or cotton fibers, although a variety of materials are contemplated by the present invention. The sheet 14 comprises either: (a) a pre-established, fast, inexpensive, and accurate chemical reaction means which produces a controlled color change, (b) a pre-established, fast, inexpensive, and accurate biosensor which produces a controlled color change, or (c) any other accurate, inexpensive, and fast technology that reacts in the presence of analyte to produce a controlled detectable signal (e.g., a color change).

The attachments to the middle 20 include a well 38 and a porous membrane 34. The well 38 is constructed in conjunction with the middle 20 to form one molded part. The well 38 is made so that the absorbent material 42 compresses to fit snugly inside. In addition, the well 38 is constructed so that the well covering 40 snaps and locks on

top of the well 38. The membrane 34 is located at the bottom of the well 38. It is made of a porous material that allows the fluid sample to pass but does not allow other debris to pass.

The attachments to the top 21 include a small window 22, large window 30, and air hole 26. The two windows 22 and 30 are open or transparent spaces that allow the sheet 14 to be viewed through the middle 20. The air hole 26 is a hole in both the top 21 and the middle 20 which allows air to escape from the base 16.

II. Delivery Systems

A. Description

The present invention provides delivery systems for assay tests that store one or more assay tests so that assay tests can be accessed on a single occasion or on two or more distinct occasions. In some embodiments, the delivery system also comprises a protective storage container making assay tests both durable and easy to access, carry, and distribute, and, in other embodiments, comprises placards that allow instructions, labels, warnings or other text or diagrams to be easily noticed and read. In still other embodiments, the delivery systems comprises additional materials, including but not limited to, co-branding materials, phone cards, etc., as described above.

The delivery system of the present invention is preferably small in size so that it can be easily carried. For example, in some embodiments, the storage container is rectangular, flat, and thin (*e.g.*, shaped like a credit card), while in other embodiments the container is round, oval, or other shapes as shown in Figure 17 (*e.g.*, with a height of approximately 5 cm or less and a diameter of approximately 2.5 cm or less), such that individuals can easily and discreetly carry the delivery systems in their pockets, wallets, or purses for use in situations away from home. In some embodiments, the delivery system is flat and comprises a folded structure. In one embodiment, the folded delivery system comprises a single fold (*e.g.*, to panels connected by a hinged portion), such that, when folded, the assay tests are provided within the folded structure. The assay tests can be associated with the folded in structure in any manner.

For example, in some embodiments, the assay tests (directly or contained within a protective encasement) are affixed to the inside of the folded structure by an adhesive. In other embodiments, the assay tests are enclosed in a pocket. In some preferred embodiments, the delivery system comprises two folds and three panels. An example of such a structure is shown in Figure 19. In some preferred embodiments, the delivery system, when folded, has a length of 8.5 cm or less, a width of 5.5 cm or less, and a thickness of 1 mm or less. In preferred embodiments, the assay tests are provided on a portion of the folded structure such that opening of first flap exposes the assay test. The use of a three-panel delivery system provides six panel sides (*i.e.*, each of the three panels has a front and back side). Delivery systems with multiple panels provide a surface area for the addition of text, figures, or attachment sites for additional materials. Such text, figures, and additional materials include, but are not limited to, branding, co-branding, instructions, information, or other attached materials (*e.g.*, phone cards, etc. as described above).

In some preferred embodiments, the delivery system is manufactured to incorporate a desiccant so that environmental moisture does not affect the biosensors or otherwise impair the reaction means of the assay. In some embodiments, a desiccant material is placed in a chamber of the delivery system or attached to an interior surface of the container (*e.g.*, lined in a plastic bottle or lined in a foil container). However, in preferred embodiments of the present invention, the desiccant material is incorporated into the material of the delivery system (*e.g.*, the entire material, the walls, the bottom, the cap, etc.). In some embodiments, the inside of the container has a plug, liner, or sleeve that is made of an entrained desiccant that channels moisture away from the inside of the container and into the desiccant thereby keeping moisture away from the tests. In preferred embodiments the desiccant is co-molded at the same time as the container allowing the desiccant to form a sleeve within the container and channeling moisture away from the contents of the container. Methods for generating such desiccant-entrained polymers are described in U.S. Patent Nos. 5,911,937 and 6,080,350, as well as PCT publications WO 98/39231, WO 99/63288, WO 99/62697, and WO 00/17259, each of which is incorporated herein by